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10/579,186	12/19/2006	Markus Ahlheim	33479-US-PCT	1535
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CORPORATE	INTELLECTUAL PRO	GUDIBANDE, SATYANARAYAN R		
=	ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080		ART UNIT	PAPER NUMBER
			1654	
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			06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	T & 11 (1 N	T			
	Application No.	Applicant(s)			
	10/579,186	AHLHEIM ET AL.			
Office Action Summary	Examiner	Art Unit			
	SATYANARAYANA R. GUDIBANDE	1654			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ti vill apply and will expire SIX (6) MONTHS fron , cause the application to become ABANDONI	N. imely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>20 A</u> /	oril 2009.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1-11 and 13 is/are pending in the app 4a) Of the above claim(s) 13 is/are withdrawn f 5) Claim(s) is/are allowed. 6) Claim(s) 1-11 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o	rom consideration.				
Application Papers					
9)⊠ The specification is objected to by the Examine	r.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/15/06, 7/2/07.	4) Interview Summar Paper No(s)/Mail [5) Notice of Informal 6) Other:	Date			

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DETAILED ACTION

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Election/Restrictions

Applicant's election without traverse of group I invention (claims 1-11), election of compound formula III (shown below) of claim 2 as species of somatostatin analog, example 8 as a species of polymer matrix, mannitol as tonicity agent, CMC-Na as the viscosity agent and polyvinyl pyrrolidone as porosity agent in the reply filed on 4/20/09 is acknowledged.

Specification

- 1. The specification of the instant application lacks the required format for presentation as provided in 37 CFR 1.77(b). The instant specification does not conform to the guidelines with sections under different titles such as:
 - (b) Cross-reference to related applications,
 - (f) Background of the invention.
 - (i) Field of the invention.
 - (ii) Description of related art including information disclosed under 37 CFR 1.97 and 1.98.
 - (g) Brief summary of the invention, etc.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

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Arrangement of the Specification

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As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (1) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).
- 2. The disclosure is objected to because of the following informalities: On page 12 in subsection 'd)', the temperature at which the viscosity of gelatin measured was disclosed as "20°C". It should read as "20°C". Appropriate correction is required.

Status of pending claims

Claims 1-11 and 13 are pending.

Claim 12 has been canceled.

Claim 13 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 4/20/09.

Claims 1-11 are examined on the merit.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 recites "LYs" in formula I. If applicant's intent was to recite the amino acid 'Lysine', then the three letter notation for 'Lysine' should be 'Lys" and not "LYs". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 1 as presented recites a variable R^1 as "wherein R^1 is optionally substituted phenyl". The variable R^1 is used as a variable for X_1 and also as part of variable R^2 . It is unclear from the claim as recited whether the definition of the variable R^1 applies to both X_1 and R^2 or to

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only X_1 . If the intent of the applicant was to use the same definition for R^1 for both X_1 and R^2 variables, then reciting the definition of the R^1 after defining the variable R^2 as shown below:

$$R_2$$
 is $-Z_1$ -CH₂-R₁, -CH₂-CO-O-CH₂-R₁, or $-C$ -OH₂-R₁

wherein R¹ is optionally substituted phenyl",

would have been appropriate.

The instant claim 1 also recites that "Lys residue of said sequence corresponding to the residue Lys⁹ of the native somatostatin-14". It is unclear from the limitation the significance of the Lys in the formula I being the Lys⁹ of the native somatostatin-14. Lysine is just an amino acid residue, it does not matter that Lys corresponds to Lys at position 9 or position 14 of the native somatostatin-14.

- 2. Claim 2 recites the limitation "a cyclic structure for the somatostatin analog as shown in formula III". There is insufficient antecedent basis for this limitation in the base claim 1. The claim 1 does not recite that the peptide of formula I is cyclic.
- 3. Claim 2 recites a limitation "wherein the configuration at C-2 is (R) or (S) or a mixture thereof". The configuration at C-2 can only be (R) or (S) and it cannot be a mixture thereof. In a single molecule, the configuration at the C-2 carbon can be either (S) or (R). It is only in the compound when synthesized that both (S) and (R) forms can form giving a mixture of individual molecules having either (S) or (R) configuration at C-2 position. The configuration at C-2 itself can only be either (S) or (R).

The proper way to recite the claim 2 would be:

"Microparticles according to claim 1 wherein the somatostatin analog is a compound of formula III wherein the compound is an (R) isomer, or an (S) isomer, or a mixture thereof, wherein the asymmetric carbon atom is the $C\alpha$ -2".

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lamberts, 2002, European Journal of Endocrinology, 146, 701-705 as evidenced by (in light of) Bruns, 2002, The Expanding Role of Octreotide II: Advances in Endocrinology and Eye Diseases, Eds SWJ Lamberts & E. Ghico, Pages 251-254.

In the instant application applicants claim a microparticle comprising a somatostatin analog comprising the amino acid sequence of formula -(D/L)Trp-Lys- X_1 - X_2 - wherein the variables X_1 and X_2 are defined in the instant claim 1.

Lamberts discloses new somatostatin analogs such as octreotide, vapreotide (RC-160) and lanreotide (BIM-23014) (all cyclic analogs of somatostatin) administered subcutaneously in a long lasting composition mixed with microspheres of DL-lactide-co-glycolyde polymer (bridging paragraph column 2 page 701 and column 1 page 702). Lambert also discloses another analog of somatostatin SOM-230 (see figure 1, page 253 from cited reference of Bruns which has been used as an evidence in the instant rejection) which is the same as the compound III of instant claim 2 wherein the variable R is –(CH₂)₂-NH₂ as shown in the figure which reads on formula III of claim 2.

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Figure 1 Structure of SOM230.

The compound of figure 1 as shown above (structure of SOM230) also reads on the formula I of instant claim 1 as follows.

For comparison purposes, the structure of formula III of instant claim 2 is shown below.

The compound in figure 1 as shown above has a 'D-Trp' amino residue and a 'Lys' residue on the right side of the molecule identical to compound of formula III of instant claim 2. The side chain on $C\alpha$ -5 in figure 1 is where R^1 is unsubstituted phenyl moiety as in formula III and meets the limitation of variable X_1 of formula I. The $C\alpha$ -6 carbon has a Phe moiety (phenylalanine amino acid) and hence meets the limitation of X_2 of formula I of instant claim 1. This reads on the limitations of instant claims 1 and 2. The polymer matrix disclosed in Lambert is a copolymer of polylactic acid and polyglycolic acid and hence reads on the instant claims 4 and 5.

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Lambert discloses the compound of formula III of instant invention which is SOM230 (page 704, column 1paragraph 3). Lambert does not explicitly discloses that SOM230 was administered mixed with Microspheres.

Since the Lambert discloses subcutaneous administration of three cyclic peptide analogs (octreotide, vapreotide and lanreotide) of somatostatin mixed with Microparticles, it would be obvious to one of ordinary skill in the art to administer SOM230, a cyclic somatostatin analog (the elected species and compound of formula III of instant invention) subcutaneously in a similar manner mixed with the Microparticles composed of DL-lactide-co-glycolide polymer.

MPEP section 2112 states that "[O]nce a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference.

The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, or on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamberts, 2002, European Journal of Endocrinology, 146, 701-705 as evidenced by (in light of) Bruns, 2002, The Expanding Role of Octreotide II: Advances in Endocrinology and Eye Diseases, Eds SWJ Lamberts & E. Ghico, Pages 251-254 in view of US 5,876,761 issued to Bodmer.

In the instant application applicants claim a microparticle comprising a somatostatin analog comprising the amino acid sequence of formula -(D/L)Trp-Lys- X_1 - X_2 - wherein the variables X_1 and X_2 are defined in the instant claim 1.

Claims 1, 2, 4 and 5 are anticipated by or in the alternative obvious over Lamberts in light of Bruns as illustrated under 35 USC 102/103 rejection set for the above.

Lambert discloses the administration of cyclic somatostatin analogs mixed with microspheres of DL-lactide-co-glycolide polymer. Lamberts do not disclose the surfactant, tonicity agent and viscosity agent associated with the Microparticles as recited in the instant claims 3 and 6-11.

Bodmer discloses octreotide pamoate (column 4, line 35 and elsewhere in the document), octreotide is a somatostatin analog as disclosed in Lamberts it reads on the instant claim 3 that

recites the somatostatin analog in pamoate salt form. Bodmer also discloses free form, salt form, complexes of somatostatin analogs with inorganic salts and hydroxides such as Ca- and Zn (column 6, lines 24-31) that reads on instant claims 1-3 and 6. Bodmer discloses polymeric carriers such as biodegradable polymers such as linear polyesters, branched polyesters, polylactic acid, polyglycolic acid, etc., and copolymers thereof (column 6, lines 54-61). This reads on instant claims 4 and 5. Bodmer discloses ionic and non-ionic surfactant that include sorbitan mono-oleate ester (column 8, line 18 and 31), reads on the instant claims 7 and 8. Bodmer also discloses mannitol (column 7, line 7) that reads on the tonicity agent and the elected species mannitol of instant claim 9. Bodmer discloses carboxy methyl cellulose (CMC-Na) and polyvinyl pyrrolidine as an emulsifying agent (column 9, lines 31-34) that reads on the viscosity agent and porosity agent respectively and reads on the instant claims 10 and 11. Bodmer disclose that sustained release formulations comprises somatostatin analog in a biodegradable polymeric carrier that reads on the instant claim 11 that recites a kit comprising somatostatin analog and a water based vehicle.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Lamberts and Bodmer to arrive at the instant invention. Lamberts discloses administration of cyclic somatostatin analogs in a microsphere of biodegradable polymers and Bodmer discloses the process of preparing Microparticles embedding the somatostatin analogs. One of ordinary skill in the art would be motivated to prepare Microparticles comprising SON230 analog of somatostatin because, as shown by Lamberts SOM230 is a universal ligand for five somatostatin receptors subtypes, i.e., with high affinity with sst₁, sst₂, sst₃ and sst₅ and with a lower affinity to sst₄ (page 704, column 1, paragraph 3). One would be further motivated to prepare microparticle

composition of SOM230 because, as illustrated by Lamberts, incorporation of somatostatin analog into Microparticles retains the activity of the somatostatin analog composition for an extended period of time. Hence it would be advantageous to improve the long lasting effect of the SOM230 analog that binds to four different somatostatin receptor binding sites with high affinity and to one receptor with lower affinity. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,876,761 (Bodmer) in view of Lamberts, 2002, European Journal of Endocrinology, 146, 701-705.

In the instant application applicants claim a microparticle comprising a somatostatin analog comprising the amino acid sequence of formula -(D/L)Trp-Lys- X_1 - X_2 - wherein the variables X_1 and X_2 are defined in the instant claim 1.

Bodmer discloses the process of production of Microparticles comprising somatostatin analog ostreotide in a polymer matrix comprising polylactide-polyglycolide copolymer.

Bodmer does not disclose the somatostatin analog SOM230 in a polymer matrix to form microparticle composition.

Lamberts discloses the SOM230 somatostatin analog and discloses composition of octreootide, vapreotide and lanreotide (cyclic analogs of somatostatin) in a composition mixed with microspheres of polylactide-polyglycolide copolymer.

It would have been obvious to one of skilled in the art to combine the teachings of Bodmer and Lamberts to arrive at the instant invention. One would have been motivated to do so given the fact that Lamberts discloses that SOM230 somatostatin is universal ligand that binds to 5 different somatostatin receptor subtypes. One would be further motivated to combine the teachings of Bodmer and Lamberts because lamberts discloses that composition of somatostatin

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combined with the Microparticles would enhance the activity of the somatostatin analog for an extended period. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 2, 4 and 5 directed to an invention not patentably distinct from claim 1 of commonly assigned U.S. Patent No. 5,876,761 (Bodmer). Specifically, as illustrated above.

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 5,876,761, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/ Examiner, Art Unit 1654